John E. Flaherty
Ravin R. Patel
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
T (973) 622-4444
F (973) 624-7070

Attorneys for Plaintiffs

Of Counsel:

Eric J. Lobenfeld
Arlene L. Chow
Peter H. Noh
Takashi Okuda
Nitya Anand
HOGAN LOVELLS US LLP
875 Third Avenue
New York, New York 10022
T (212) 918-3000
F (212) 918-3100

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants.	:	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiffs Takeda Pharmaceutical Company Limited ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A."), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Plaintiffs" or "Takeda"), as and for their Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Limited ("Cadila") (together, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products. Takeda Japan manufactures lansoprazole orally disintegrating tablets.

2. Plaintiff Takeda Japan is the owner of record and assignee of U.S. Patent No. 9,901,546 ("'546 Patent" or "the patent-in-suit").

3. Plaintiff Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application ("NDA") No. 21-428. In addition, Takeda U.S.A. has the exclusive right to import lansoprazole orally disintegrating tablets into the United States. Takeda U.S.A. purchases from Takeda Japan and imports into the United States, lansoprazole orally disintegrating tablets manufactured by Takeda Japan.

4. Plaintiff Takeda America is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda America is involved in the purchase, sale, and marketing of pharmaceutical products. Takeda America has the exclusive right to purchase lansoprazole orally disintegrating tablets from

Takeda U.S.A. and sell those tablets to the public in the United States. Takeda America sells lansoprazole orally disintegrating tablets manufactured by Takeda Japan that it purchases from Takeda U.S.A. to the public in the United States.

5. On information and belief, Zydus is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

6. On information and belief, Cadila is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

7. On information and belief, Zydus is a wholly owned subsidiary of Cadila.

8. On information and belief, Zydus is controlled and/or dominated by Cadila.

9. On information and belief, Cadila conducts its North American operations, at least in part, through Zydus.

10. On information and belief, Zydus and Cadila operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331

and 1338(a).

12. Zydus is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation in New Jersey, its regular and established place of business in this District, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts within the State.

13. On information and belief, Cadila regularly transacts business within this District and derives substantial revenue from services or things used or consumed in this jurisdiction, including but not limited to directing the operations and management of Zydus, as well as shipping pharmaceuticals to Zydus from locations outside the United States for distribution by Zydus within the United States generally, and within this District specifically.

14. On information and belief, Zydus acts as an agent of Cadila with respect to the acts complained of herein.

15. On information and belief, the acts of Zydus complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of Cadila, and, in part, for the benefit of Cadila.

16. On information and belief, Cadila directed Zydus to perform the acts complained of herein, in whole or in part, to shield itself from liability for patent infringement based upon those acts.

17. On information and belief, Cadila and Zydus know and intend that, following any approval of Abbreviated New Drug Application ("ANDA") No. 200816, including any amendments thereto, Defendants' ANDA Product will be distributed and sold in New Jersey.

18. Zydus' acts and contacts with this District, as an agent of Cadila, are attributable to Cadila for jurisdictional purposes.

19. Cadila is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation of Zydus in New Jersey, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts within the State.

20. Cadila and Zydus are also subject to personal jurisdiction in this District because, on information and belief, Cadila and Zydus acted collaboratively in the preparation and submission of ANDA No. 200816, including any amendments thereto, to the United States Food and Drug Administration ("FDA") for the purpose of obtaining approval to distribute and sell Defendants' Proposed ANDA Product throughout the United States, including in New Jersey.

21. Cadila and Zydus are also subject to personal jurisdiction in this District because they purposefully availed themselves of the benefits and protections of this Court by previously initiating litigation in this District. *See, e.g., Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. v. Gilead Scis., Inc.*, No. 14-7080 (FLW)(LHG) (D.N.J.). Cadila and Zydus have also been sued in this District, including by Takeda, without objection that this Court lacks personal jurisdiction over them. *See Takeda Pharmaceutical Co. Ltd. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 18-01994-FLW-TJB (D.N.J.); *Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 10-01723-JAP-TJB (D.N.J.).

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

23. On February 27, 2018, the United States Patent and Trademark Office ("PTO") issued the '546 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Ltd., the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and

Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '546 Patent. A copy of the '546 Patent is attached hereto as Exhibit A.

24. On August 30, 2002, the FDA approved NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Plaintiff Takeda U.S.A. is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which Plaintiff Takeda America sells under the name Prevacid® SoluTab™.

25. The patent-in-suit is among the patents listed in a FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") for Prevacid® SoluTab™, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg.

26. On information and belief, through the coordinated efforts of its staff worldwide, including in India and the United States, Cadila seeks to constantly expand the range of generic products it sells.

27. On information and belief, Cadila and Zydus collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of New Jersey specifically.

28. On information and belief, Cadila actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

29. On information and belief, Cadila reviewed the Orange Book patents for Prevacid® SoluTab™ and certain commercial and economic information relating to Prevacid® SoluTab™, including estimates of the revenues generated by the sale of Prevacid® SoluTab™,

and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release orally disintegrating tablets.

30. On information and belief, Cadila and Zydus collaborated in the research, development, preparation, and filing of ANDA No. 200816 for lansoprazole delayed release orally disintegrating tablets.

31. On information and belief, Zydus submitted to FDA ANDA No. 200816 seeking approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, prior to the expiration of the Orange Book patents for Prevacid® SoluTab™.

32. Plaintiffs received a letter from Zydus, dated February 19, 2010, notifying Plaintiffs of ANDA No. 200816 and that ANDA No. 200816 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Zydus' opinion, no valid, enforceable claim of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), U.S. Patent No. 7,399,485 ("'485 Patent"), and U.S. Patent No. 5,463,632 ("'632 Patent") would be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 200-816.

33. On April 5, 2010, Plaintiffs filed suit in this District against Defendants for infringement of the '994 Patent, '942 Patent, and '632 Patent, based upon, *inter alia*, Zydus' written notification of its filing of ANDA No. 200816 and accompanying Paragraph IV certification. *See Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 10-01723-JAP-TJB (D.N.J.). That suit was resolved on October 16, 2014. *Id.* (D.I. 389).

34. On information and belief, Defendants subsequently submitted to FDA an amendment to ANDA No. 200816 ("Amended ANDA No. 200816") in order to modify the formulation of their ANDA Product. On information and belief, Amended ANDA No. 200816 specifically seeks FDA approval to market Defendants' ANDA Product prior to the expiration of the Orange Book patents for Prevacid® SoluTab™, including the patent-in-suit.

35. Plaintiffs received a letter from Zydus, dated January 3, 2018, notifying Plaintiffs of Amended ANDA No. 200816 and that Amended ANDA No. 200816 included a Paragraph IV certification that, in Zydus's opinion, no valid, enforceable claim of the '994 Patent, '942 Patent,'485 Patent, or U.S. Patent No. 7,875,292 ("'292 Patent") will be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in Amended ANDA No. 200816.

36. On February 12, 2018, Plaintiffs filed suit in this District against Defendants for infringement of the '994 Patent, '942 Patent, '292 Patent, and '485 Patent, based upon, *inter alia*, Zydus' filing of Amended ANDA No. 200816 and Zydus' written notification of its filing of Amended ANDA No. 200816 and accompanying Paragraph IV certification. *See Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 18-1994-FLW-TJB (D.N.J.). That suit is currently pending in this District.

37. Plaintiffs further received a letter from Zydus, dated May 31, 2018, notifying Plaintiffs that Amended ANDA No. 200816 included a Paragraph IV certification that, in Zydus's opinion, no valid, enforceable claim of the '546 Patent will be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in Amended ANDA No. 200816.

38. On information and belief, Cadila made the ultimate decision to file Amended ANDA No. 200816 with FDA, and encouraged and directed Zydus to file Amended ANDA No. 200816 and the Paragraph IV certification, and Zydus did so at Cadila's direction.

39. On information and belief, Cadila was necessarily aware of the patent-in-suit when it directed Zydus to file the Paragraph IV certification.

40. On information and belief, Zydus and Cadila continue to collaborate in seeking approval of Amended ANDA No. 200816 from FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed release orally disintegrating tablets (including commercial marketing and sale of such products in the State of New Jersey) in the event that FDA approves Amended ANDA No. 200816.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '546 Patent by Zydus and Cadila)

41. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 40 hereof, as if fully set forth herein.

42. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '546 Patent.

43. By filing Amended ANDA No. 200816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of the lansoprazole delayed release orally disintegrating tablets described therein prior to the expiration of the '546 Patent with pediatric exclusivity, Defendants have infringed the '546 Patent under 35 U.S.C. § 271(e)(2).

44. Defendants continue to seek approval of Amended ANDA No. 200816 despite being aware of the '546 Patent and knowing that such action would constitute infringement of the '546 Patent.

45. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the ’546 Patent.

46. Defendants’ conduct renders this case “exceptional” within the meaning of 35 U.S.C. § 285.

47. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’546 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the ’546 Patent by Cadila)

48. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if fully set forth herein.

49. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the ’546 Patent.

50. By reason of Cadila’s inducement of Zydus’ direct infringement of the ’546 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

51. On information and belief, Cadila’s inducement of Zydus’ direct infringement of the ’546 Patent will continue unless enjoined by this Court.

52. Plaintiffs have no adequate remedy at law for Cadila’s inducement of Zydus’ direct infringement of the ’546 Patent.

53. Defendants’ conduct renders this case “exceptional” within the meaning of 35 U.S.C. § 285.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Zydus and Cadila have infringed the patent-in-suit;

B. An order adjudging and decreeing that Cadila has induced infringement of the patent-in-suit;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of Amended ANDA No. 200816 be no earlier than the expiration date of the patent-in-suit, including any extensions and/or exclusivities;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the lansoprazole products described in Amended ANDA No. 200816 or any other ANDA not colorably different from Amended ANDA No. 200816 until the expiration date of the patent-in-suit, including any extensions and/or exclusivities;

E. A declaration that this case is exceptional and an award of attorneys' fees pursuant to 35 U.S.C. § 285 and costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: July 18, 2018

By: *s/ John E. Flaherty*

John E. Flaherty
Ravin R. Patel
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(972) 622-4444

Attorneys for Plaintiffs

Of Counsel:

Eric J. Lobenfeld
Arlene L. Chow
Peter H. Noh
Takashi Okuda
Nitya Anand
HOGAN LOVELLS US LLP
875 Third Avenue
New York, New York 10022
T (212) 918-3000

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that certain patents related to the patent at issue in the above captioned action are the subject of the following action pending in this District: *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc.*, No. 18-1994-FLW-TJB (D.N.J.).

Respectfully submitted,

Dated: July 18, 2018

By: *s/ John E. Flaherty*

John E. Flaherty
Ravin R. Patel
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(972) 622-4444

Attorneys for Plaintiffs

Of Counsel:

Eric J. Lobenfeld
Arlene L. Chow
Peter H. Noh
Takashi Okuda
Nitya Anand
Hogan Lovells US LLP
875 Third Avenue
New York, New York 10022
T (212) 918-3000

Attorneys for Plaintiffs